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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,869	03/26/2004	Osama Kandil	KAN-001-B	7603

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ALEXANDRIA, VA 22314

EXAMINER
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JEAN-LOUIS, SAMIRA JM

ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
07/10/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/809,869

Applicant(s)

KANDIL, OSAMA

Examiner

Samira Jean-Louis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7, drawn to a topical composition comprising a polyunsaturated fatty acid fraction extracted from *Nigella sativa* L. seeds and a pharmaceutically acceptable carrier, classified in class 424, subclass 401.
  - II. Claim 8, drawn to a method of treating an anal fissure or hemorrhoid with said composition, classified in class 424, subclass 401.
  - III. Claims 9-11, drawn to methods of treating a skin condition with said composition, classified in class 424, subclass 401.
  - IV. Claim 12, drawn to a method of treating or preventing inflammation with said composition, classified in class 424, subclass 401.
  - V. Claims 13-25, drawn to a methods of treating or preventing an infection with said composition, classified in class 424, subclass 401.

The inventions are distinct, each from the other because of the following reasons: Inventions I and (II-V) are related as a composition and methods of use of said composition. These inventions as claimed can be shown to be distinct if either or both of the following can be shown: 1) the methods for using the composition as claimed can be used with other materially different products or 2) the composition as claimed can be used in a materially different processes (See MPEP 806.05 (h)). In this particular

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instance, the processes claimed by applicant can be practiced with a materially different product, such as an encapsulated pill.

Consequently, due to the reasons listed above, these inventions are distinct and a search required for Group I (i.e. the topical composition) is not required for Group II-V (i.e. the methods of treatment using said composition). In addition, while the searches for Group I and II-VI may be overlapping, in searching Group I, the Examiner will solely base the search on the patentability of the aforementioned composition. Conversely, in searching for Group II-VI, the Examiner will specifically focus the search on the patentability of one of the methods of treatment using said composition. Accordingly, a search for both groups would pose an undue burden on the Office (see MPEP § 808.02).

### ***Species Election***

In addition, this application contains claims that are directed to more than one species of the generic inventions. Thus, once applicant has selected a specific type of invention to be examined, applicant will need to further select the specific species associated with the chosen invention. Moreover, this species election is required for both group I and groups II-V listed above.

Thus, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-25 are generic.

Specifically, in claim 2 (Group I), applicant is required to elect the formulated form of said composition.

In claim 5 and 15 (Groups I-V), applicant is required to specifically elect a type of an essential polyunsaturated fatty acid.

In claim 11 (Group III), applicant is required to elect a condition from the group of conditions listed in claim 11.

In claim 21 (Group V), applicant is required to state whether one or more compounds will be utilized in said method. Once applicant has specifically stated the intended number of compound(s) to be used, applicant is then required to elect a particular compound out the group listed in claim 21.

Finally, applicant is required to state a particular type of infection to be examined and then elect a particular genus species out the elected infection groups listed for both claims 23 and 24 (Group V).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-5 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER